July 6, 2020

Meghan Cupp
NDA Partners, LLC
Representing: PrivaPath Diagnostics, Inc.
40 Commerce Lane, Suite D
Rochelle, VA 22738

Re: EUA201043/A002
Trade/Device Name: LetsGetChecked Coronavirus (COVID-19) Test
Dated: June 25, 2020
Received: June 26, 2020

Dear Ms. Cupp:

This is to notify you that your request to update the authorized labeling of the LetsGetChecked Coronavirus (COVID-19) Test to add the Hologic Aptima SARS-CoV-2 Assay (Panther System) per the Instructions for Use (without modification), in addition, to an RNaseP gene RT-PCR as alternative assay for use in the PrivaPath workflow for processing nasal swab specimens self-collected by individuals at home, is granted. Upon review, we concur that the information submitted in EUA201043/A002 supports the requested updates for use with the LetsGetChecked Coronavirus (COVID-19) Test. We concur with the associated updates to the EUA Summary and Standard Operating Procedure: RP Gene Detection using Thermo Fisher Applied Biosystems RT-PCR (Control for Patient Self Collected Specimens), in addition to some other minor updates to the EUA summary for clarification. By submitting this amendment for review by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the LetsGetChecked Coronavirus (COVID-19) Test issued on May 28, 2020.

Sincerely yours,

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Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health